SUMMARY

ESSTECH® MULTI TORIC Aspheric (multifocal)
(hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear
(clear and tinted)

1. Submitted by:	Les Laboratoires Blanchard Lentilles De Contact 1552, rue King ouest, suite 200 Sherbrooke, QC J1J 2C3 Canada
Contact: Official agent	John M. Szabocsik, Ph.D. Szabocsik and Associates 203 N. Wabash, Ste 1200 Chicago, IL 60601 (312) 553-0828
2. Date prepared:	October 3, 2000
3. Device: Common Name	ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted)
Trade Name	ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted)
4. Classification	Class II (Performance Standards) 21 CFR 886.5925, 86LPL Lenses, Soft Contact, Daily Wear
5. Substantial equivalence	This lens is identical in design to the ESSTECH® MULTI Aspheric (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear, K982904, September 1, 1998, excepting for the addition of a toric feature.
6. Device description	The ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted) is available as a multifocal lens with an aspheric front surface for the correction of visual acuity in presbyopic persons who are myopic or hyperopic. The posterior surface of the ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted) has a toric surface generated for the purpose of correcting vision in an eye that has up to 4.50 diopters of astigmatism. The lens is constructed to provide optimum edge thickness and contour, with the central area providing the reading power in the equivalent of a 2.50 diopter near addition. The aspheric front curve undergoes a progressive power change, resulting in intermediate and distance power outward from the center. The ESSTECH® MULTI TORIC

Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted) is designed with a "double slab-off flange ballast" stability feature.

The lens is a flexible transparent shell of the following dimensions:

Chord diameter:	14.4mm to 14.8mm
Center thickness:	0.07mm to 0.25mm
Base Curve:	8.00mm to 9.20mm
Power:	-5.00D to +9.00D (in 0.25D steps)
Cylinder:	up to -4.50D (in 0.25D steps)
Axis:	1^0 to 180^0 (in 1^0D steps)

The lens material, hioxifilcon B, is a hydrophilic co-polymer of glycerol methacrylate (GMA) and 2-hydroxyethyl methacrylate (2-Hema), crosslinked with ethylene glycol dimethacrylate. The lens is swollen to equilibrium state in sterile buffered saline solution, and contains 48% water by weight when fully hydrated.

7. Indications for Use

The ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia), presbyopia and astigmatism up to 4.50 diopters in not-aphakic persons with non-diseased eyes. Eyecare practitioners may prescribe the lens for daily wear in a Planned Replacement Program. The lens may be disinfected using heat, chemical or hydrogen peroxide disinfecting systems.

8. Comparison to predicate device: see following table

SUBSTANTIAL EQUIVALENCE

	Esstech® Multi Asphere (K982904)	Esstech® Multi Toric Asphere
Material	hioxifilcon B	hioxifilcon B
Refractive index	1.404, hydrated	1.404, hydrated
Light transmittance	>95% clear >95% blue tint	>95% clear >95% blue tint
Surface characteristics	hydrophilic, spherical back curve, aspheric front curve	hydrophilic, toric back curve, aspheric front curve

SUBSTANTIAL EQUIVALENCE (continued)

	Esstech® Multi Asphere (K982904)	Esstech® Multi Toric Asphere
Water content	48% by weight in normal buffered saline	48% by weight in normal buffered saline
Oxygen permeability	15 (cm^2/sec)(ml O_2/ml x mmHg@35°C) (revised Fatt method)	15 (cm^2/sec)(ml O_2/ml x mmHg@35°C) (revised Fatt method)

9. Chemistry and Manufacturing

There were no changes to the chemistry of the lens.

Manufacturing changes included the addition of a toric feature to the multifocal lens. A flow chart and a description of the changes are attached.

Ten (10) ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lenses were manufactured according to prescription, and shown to be within acceptable standards by the ordering clinician. The report is attached.

10. Toxicology

No changes were made that would impact toxicology.

11. Microbiology

No changes were made that would impact microbiology.

12. Clinical Studies

As mentioned in prior premarket notifications, all clinical information is by reference to K964528 - BENZ-G 3X (hioxifilcon B) Spherical and Toric Soft Lenses.

13. Shelf-Life

No changes were made that would impact Shelf-life.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

John M. Szabocsik, Ph.D.
Szabocsik and Associates
203 North Wabash Avenue
Suite 1200
Chicago, IL 60601

Re: K003161
Trade Name: ESSTECH MULTI TORIC Aspheric (multifocal) (hioxifilcon B)
Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted)
Regulatory Class: II
Product Code: 86 LPL
Dated: October 6, 2000
Received: October 10, 2000

Dear Dr. Szabocsik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market..

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER (IF KNOWN) K 003161

DEVICE NAME ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted)

INDICATIONS FOR USE

The ESSTECH® MULTI TORIC Aspheric (multifocal) (hioxifilcon B) Soft (hydrophilic) Contact Lens for Daily Wear (clear and tinted) is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and/or presbyopia) and astigmatism up to 4.50 diopters in not-aphakic persons with non-diseased eyes. Eyecare practitioners may prescribe the lens for daily wear in a Planned Replacement Program. The lens may be disinfected using heat, chemical or hydrogen peroxide disinfecting systems.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Lee Cohn MD

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K 003161